

# **SPL Process Meeting Meeting Minutes July 31, 2013**

Chair of today's meeting: Pat Cowall-Hanover

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

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Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

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Leadership Team -- Discussion Topics:

1. D&B data:

- FDA has been seeing a trend that some companies are continuing to ask for overrides for their SPL files because of DUNs validation errors. They want to encourage sponsors to work with DUNS to correct the data so that they won't get validation errors.

Background:

The SPL manual overrides were supposed to be a temporary solution while the sponsor worked with D&B to resolve the issue. In the manual override request e-mails, some companies have stated each time that they are still working with D&B. Some companies have stated the same for almost four years.

- o Appears that some companies are just requesting manual overrides and are not attempting to fix the issue with D&B
- o FDA manually checks the D&B database and will not manually load a file if they notice that the company has intentionally entered incorrect information.
- o Manual overrides are done for establishment registration SPL files (not applicable to the product SPL files)

At any time, FDA could state the manual overrides are no longer permitted because the companies should have had enough time to fix their data. (We haven't had any info that this is in the plan.)

FDA seems to be willing to intervene with D&B on behalf of the sponsor.

- o If it turns out that the D&B data needs to be fixed even after multiple requests by the company to D&B, then FDA could contact D&B to report the issue as was done for one company last week.

Current project:

- Lonnie and John Gardner have been working with DUNS to figure out issues. They want to help sponsors to correct their data.
- They don't understand why sponsors are having such difficulty correcting their data. Thus they are requesting examples of what issues sponsors are seeing.
- Lonnie is developing a list of common errors/problems. Some errors include:
  - o Using headquarters instead of specific establishment.
  - o Translation of foreign addresses into English (D&B global database is in English)
  - o More than 1 entity at the same location. Each entity has its own DUNS number.
    - If you have multiple DUNS at a site, they need to pick one and always use the same one to communicate to the FDA.

Discussion:

Dale from Merck is one of the people who keep asking for overrides. She got a call from Stephanie from the D&B Washington office. Dale sent her file to Stephanie and they were going to look at the file and Dale would be part of a pilot.

She doesn't know what the issues are with her file – mostly with foreign countries. Dale lanetti will provide progress reports.

2. New validation of name/DUNS Number relationships:

- Major improvement: 100% automated.
- Starting 7/22 – completely automated the acknowledgement and error messages.
- Error message should come at the same time. 100 % automated.
- Even on holidays and weekends.

Discussion:

Howard Shatz: Does this include any flexibility built in to the automated validation of the name/DUNS Number? For example if the D&B name is A.B.C. Corp. and the name in the SPL is entered as ABC Corp, will that pass validation?

Current assumption is that until now anything automatically failing validation was reviewed manually before notifying the submitter of the error, in case there was a variation in the name not programmed in. If now there is variation programmed in, it would be helpful to know what that is in case an error is received that can be addressed through an adjustment to the company name in the SPL when the client is ok with the name as it currently exists in the D&B database.

3. SPL Section Headers and Titles

- Sponsors are using section headers incorrectly. FDA is requesting that labelers review their SPL and use the right section header. If not, someone will contact you to fix it. Common section header errors are:
  - o Box warnings
  - o Medication guide
- People were using a Boxed warning heading when they wanted a box around text at other places in the content of labeling.
  - o Ie People need to use section loincs for the type of data – not formatting.
- People are putting Medication Guides as part of section 17 (Patient Information), part of the How Supplied section or in the PPI section. – when it should be coded as a separate section.

- The new stylesheet has been changed to allow titles to be entered for each section -- ie this information will not render in the ToC. Thus, all titles may now be populated into the SPL – esp MedGuide and PDP sections. (Jackie Mohns)

#### 4. Optional **CDER** NDC Labeler Code Request Data Elements:

The labeler SPL now contains optional data elements.

- Old SPL version: Right now the SPL contains only the name and DUNS number of the labeler. The sponsor submit SPL request, and CDER sends email requesting more info
- New SPL version: Optional info in the SPL labeler SPL would include the complete labeler code address. Sponsors can now provide additional information in original request, instead of having to respond to a separate correspondence.
- Optional business operation qualifier (FDA requests that this be included). FDA want to differentiate between
  - o Distributors of drug product under its own private label, or
  - o Manufacturers who market drug product under its own label, by
    - human Rx
    - OTC

#### 5. CDER-regulated product SPL - Marketing Start/End Date for Packages

- CDER is planning to allow companies to add optional start and end date for the trade package (ie no dates on inner components).
- **CDER regulated products only** – including OTC and generics and bulk ingredients.
- Not on products CBER and CVM products.
- Optional
- Coding: No new coding. Just repurposing the current coding. Take the same marketing info and put it on the outer package. Put it under the container package code.
- Validation issues: Logical validation rules. You need to code it correctly and dates have to be right (ie package start and end dates)
- When can we start implementing this? Validation will start this fall.
- **Followup: Timing (per Lonnie Smith): approximately October/November.**

#### 6. Med Guide project: Jackie Mohns

- There are issues with the Medication Guides.
  - o Medication Guides incorrectly coded
  - o Products that are “missing” Medication Guides
- Lonnie may conduct another training program to determine what the sections of the SPL are intended to be.
- Downstream SPL group has started a project to help resolve the issues with Med Guides. They
  - have been reviewing the list to identify the issues within the SPLs and Medication Guide Sections and provide comments/recommendations for resolution. They are reviewing the list of errors
  - Taken off the repackagers who use branded SPL as their basis
- They have posted a list on their wiki.

<http://spl-work-group.wikispaces.com/Downstream+Uses+of+SPL>

[DUSPLSCR@gmail.com](mailto:DUSPLSCR@gmail.com)

- We will forward announcing the Medication Guide “Clean up” project

## Other Topics:

### 7. New FDA updated SPL Stylesheet and its impact to submissions

The FDA Data Standards Council's Structured Product Labeling (SPL) web page has been revised to include an updated SPL stylesheet:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Changes include the following (additional information added per followup with Lonnie:

- Rendering of most recent highlights text revision date excluding Data Elements Section and all sections past section 17.
  - highlights revision date no longer being pulled from effective time – it's pulled from whatever section was changed most recently
  - The highlights date will pick up latest revision date in sections 1-17.
- Added support for Substance Indexing
  - Updated to display the substance indexing information. There is a substance indexing file – like the other indexing files. The substance index contains Information about substance – eg all the product names, chemical structure etc. The stylesheet now has functionality so that people can link to more information about the substance.
- Render Marketing Start Date and End Date at the package level in the package table.
  - when will this be implemented – approx. Oct/Nov.
  - Implementation of this is optional
  - Vendors will have to update their software to allow sponsors to enter this date.
  - We encourage you to use this function because NCPDP reimburses on the last lot.
  - NDC used to disappear from the NDC director. Now, this isn't a problem. The expiration date is still retained in the NSDE file?
- Exclude sections after Section 17 from the FPI table of contents.
  - These sections now be excluded from being printed in the ToC.
  - Lonnie is encouraging everyone to put titles in for all sections of the SPL.
- No preceding zero if the month is a single digit.
  - The date in the highlights section will be printed without the leading zero.
  - For example: Revision Date: 4/2013
- Support use of Labeler Code Request Labeler Detail Information data elements
  - See discussion topic number 4 above. Sponsors can now include additional information in the CDER labeler code request – instead of providing this information in follow-up correspondence with FDA.
- Support the Labeler Code Request - Animal Drug
  - CVM maintained the original structure of the SPL labeler code request. Needed to create separate document type for SPL Animal Drug Labeler Request.
- For 508 compliance, add column and row tagging for tabular data elements
  - i.e., those tables which are data tables, not just for layout.
  - Product Data Elements– This data is displayed with the other sections of the SPL file. FDA decided that that the easiest way to display this data is in a table format. Since this “table” is just a display of this product data, there is no requirement to make this “table” section 508 compliant. Even though there is no requirement, FDA decided to make this data “table” compliant with section 508. Thus the stylesheet needed to be adjusted to accommodate this.
- Medical foods erroneously had a disclaimer.

- The SPL file had an erroneous disclaimer – and this disclaimer was removed from the stylesheet.
  - Allow hiding (toggle show/hide) the Core Content of Labeling
    - "mixin" (e.g., for PET drugs)
    - Note: not easy way to explain this. More info will be available in the future
  - Minor CSS stylesheet improvement, turning solid white background into transparent background.
    - Basic formatting change to background color
8. There is a bulk product that's being shipped from a foreign country to our US facility for analytical testing/transit study/packaging trials. The ANDA still hasn't been transferred to us. The ANDA will continue to make the ANDA product for us. Could you please let us know if this product needs to be drug-listed for customs clearance or if there is something that the current ANDA holder needs to do? (Ranjith Abraham)

Discussion:

- You need to have the manufacturer of the product drug list the product with a code of "Drug for Further Processing".
- When you ship product for testing purposes only, the shipment label will have to be labeled for testing only. It will not need to be drug listed. But this material won't be able to be used in trade product.
- After the product is going to be used in products, then the product will have to be drug listed appropriately – by the foreign manufacturer – using their labeler code and their NDC code.
- The foreign manufacturer will also have to list your company on their establishment registration (DER) as an importer.
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## Feedback for D&B issues:

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- 2009 crude validation against a 9 digit number.
- 2010Dec onwards started validating name and address of each establishment
- Issues arose with D&B database that FDA uses to validate, and FDA started having to do manual overrides.
- FDA is trying to figure out how to manually load fewer files, especially since new mandate of submitting DERs between Oct and December for the following year.

### Known issues:

- Issues – main data:
  - Manual uploads – every time it didn't validate
    - Use the headquarters DUNS number instead of facility DUNS number.
    - Name different in foreign countries
    - Address on letterhead is different than D&B address, either need to change address on letterhead or register factory as separate entry.
- Key issue is that D&B database is a mystery – we don't have access to the data in the D&B system. So we don't know there is an issue.
  - Not efficient in today's environment
  - Already have a validator lite tool.
  - Sponsors like to fix things before they get to FDA.
- Validation process.
  - They have a copy of the D&B file (monthly file)....and then they go to the global database.
  - They want the ability to go out and see the D&B data.
- John Gardner is working D&B is working for a solution.
  - Pushing for pilot D&B solution to be implemented
  - Pushing for better info in D&B data
  - Update to FDA site to provide access D&B site
  - Propose to get something out there before Oct 1, when people need to submit their DER.
- Ideas. Can FDA provide a company a snapshot of their data.
  - Legitimate solution - FDA can do this with FDA's current D&B license.
  - Relief until D&B's pilot is available.

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### Specific Examples from Industry

1 Melissa Ignatowski  
Regulatory Electronic Submission Coordinator  
Lannett Company, Inc.

- 1) Somehow, our company DUNS numbers and their assigned locations change — there are three companies. The numbers are resorted to the incorrect building locations. This is happening on the D&B end. We still don't know how this keeps happening.

- 2) One of our company numbers was rendered “defunct” by D&B, and we had to wait for a new number. Somehow, the D&B system rendered one of our DUNS numbers obsolete. We still don’t know how this happened.
- 3) The D&B Web site, which we use to check company numbers, is not updated and displays the incorrect numbers. This is a primary source to check information; why can’t D&B get it right?
- 4) Trying to resolve DUNS number issues takes several weeks. For the last three (3) years, we have spent an average of six (6) weeks trying to re-establish our company DUNS numbers.
- 5) Although the customer service reps are pleasant, D&B has terrible customer service. They seem to have a very blasé attitude when correcting DUNS numbers, and they VERY RARELY return calls or e-mails. This contributes to a very lengthy and frustrating experience.

All of these factors collide with the FDA-imposed filing deadlines, which is why we have requested manual overrides.

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2. Dale Ianetti – How can you tell what the actual error is?
  - On the D&B site – you can check out an individual DUNS number – in the publicly available database. It is a start.
  - But this database may not be the same database that is used by D&B. This is the issue.
  - Finance or purchasing department of your company may have a contract with D&B
  - If you give Lonnie the core ID, Lonnie will give you the exact error message and confirm what the problem is.

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3. Sanofi (Natalie Draus):
  - You can also get a download of the family tree of your company’s data from D&B.
  - Even if they are using the exact address of the manufacturing site for the site associated with the FEI, they still get an error. They don’t find any difference in the data provided.
    - 3 sites flagged.